

Hydrogen Peroxide & Peroxyacetic Acid  
PC Code: 000595 & 063201  
Type of Review: Label Amendment/Toxicology Rationales

DP Number: 440166  
EPA File Symbol No.: 81803-6



**UNITED STATES ENVIRONMENTAL PROTECTION AGENCY**  
WASHINGTON, D.C. 20460

OFFICE OF CHEMICAL SAFETY  
AND POLLUTION PREVENTION

**MEMORANDUM**

**DATE:** June 12, 2017

**SUBJECT:** Science Review in Support of Product Label Amendments for Jet-Ag (EPA Reg. No. 81803-6),  
Containing 26.5% Hydrogen Peroxide and 4.9% Peroxyacetic Acid As Its Active Ingredients.

<b>Decision Number:</b>	529128
<b>Submission Number:</b>	1002975
<b>DP Number:</b>	440166
<b>EPA Registration Number:</b>	81803-6
<b>Chemical Class:</b>	Biochemical
<b>PC Code:</b>	000595 & 063201
<b>CAS Number:</b>	7722-84-1 & 79-21-0
<b>Active Ingredient Tolerance Exemptions:</b>	40 CFR 180.1197 & 40 CFR 180.1196
<b>MRID Numbers:</b>	None

**FROM:** Russell S. Jones, Ph.D. Senior Scientist  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

/s/ 06/12/2017

A handwritten signature in black ink, likely of Russell S. Jones, is written over the date and signature line.

**THROUGH:** Miachel Rexrode, Ph.D. Senior Scientist  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

/s/

*Miachel Rexrode 6/13/2017*

**TO:** Alex Horansky, Regulatory Action Leader  
Biochemical Pesticides Branch  
Biopesticides & Pollution Prevention Division (7511P)

/s/

*Alex Horansky 6/30/2017*

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## ACTION REQUESTED

On behalf of Jet Harvest Solutions, M. Priest (TSG, Inc.) requests amendments to the product label for Jet-Ag (EPA Reg. No. 81803-6) for the purpose of changing the precautionary statement for oral exposure from “May be fatal if swallowed” (Toxicity Category II) to “Harmful if swallowed” (Toxicity Category III). In support of the label amendments to change the acute oral toxicity category from II to III, the applicant submitted rationales for acute oral toxicity (OCSPP 870.1100) and acute dermal toxicity (870.1200), a Confidential Statement of Formula (CSF, dated 08/26/2016), and a draft revised product label.

## RECOMMENDATIONS AND CONCLUSIONS

1. The request to change the precautionary statement on the product label for Jet-Ag (EPA Reg. No. 81803-6) from “*May be fatal if swallowed*” to “*Harmful if swallowed*” is acceptable, and agrees with the Toxicity Category III classification for both Hydrogen Peroxide and Peroxyacetic Acid as specified in the Peroxy Compound RED of 1993.
2. Due to the Toxicity Category I (Corrosive) classification for dermal irritation, the precautionary statement “*Causes skin burns...*” must remain on the Jet-Ag product label.
3. Due to the corrosive effect upon the skin, it is unlikely that the active ingredients would be appreciably absorbed through the skin. Therefore, the request to change the existing precautionary statement “*May be harmful if absorbed through skin....*” May be removed.
4. Although the information cited by the applicant for each ingredient in the formulation indicated that each ingredient could be classified individually in Toxicity Category III for acute oral toxicity, it cannot be assumed that the formulated product containing a mixture of these ingredients would not have unknown additive and/or synergistic effects that would result in lower Toxicity Categories for acute dermal toxicity and dermal irritation.
5. The Agency-required changes made to the Jet-Ag (EPA Reg. No. 81803-6) product label will bring in into agreement with the precautionary statements on the current PERACLEAN ® 5 (EPA Reg. No. 54289-3) product label, which is identical in formulation to Jet-Ag.

## BACKGROUND

The subject product, Jet-Ag (EPA Reg. No. 81803-6) is identical to PERACLEAN ® 5 (EPA Reg. No. 54289-3), a product that is registered in the Antimicrobials Division (AD) and is intended for use as a disinfectant/sanitizer on “Previously Cleaned Non-Porous Food Contact Surfaces” and “Hard Surfaces.” Jet-Ag is registered in BPPD and is intended for use as a “Fungicide, Bactericide, and Algacide for Agricultural Uses.”

The Signal Word currently listed on both product labels is “DANGER.”



Alpha Methyl Mannoside  
PC Code: N/A  
Type of Review: Product Chemistry, Toxicology

DP Number: 435557  
EPA File Symbol No.: 48813-G

The subject product, Jet-Ag, lists Toxicity Category II Precautionary Statements for oral toxicity and dermal toxicity ("*May be fatal if swallowed or absorbed through the skin*" and "*Do not get...on skin or on clothing*"). The latest product label for PERACLEAN ® 5 lists a Toxicity Category III Precautionary Statement for oral toxicity ("*May be harmful if swallowed*") and Toxicity Category I Precautionary Statement for dermal toxicity ("*Corrosive...causes skin burns*" and "*May be fatal if...absorbed through the skin*" and "*Harmful if swallowed*"). The latest product label update/amendment for PERACLEAN ® 5 (EPA Reg. No. 54289-3) occurred in March 2017 [see letter from J. Hebert (Chief, RMB1/AD) to T. Rosamilia (Manager, Evonik Corp.) dated 03/27/2017]. The update/amendment of the PERACLEAN ® 5 product label pertained to updated label use information (not specified in the letter).

## RATIONALE SUMMARIES

Guideline studies were not submitted. In lieu of Guideline studies, the applicant submitted separate rationales in support of the data requirements for Acute Oral Toxicity (OCSPP 870.1100) and Acute Dermal toxicity (OCSPP 870.1200). Although worded somewhat differently, the information presented in each rationale is the same. The basis of the rationales is that the active ingredients are already in acute oral toxicity Category III (citing the EPA RED Facts sheet for Peroxy Compounds, dated 1993), as well as other information cited by the applicant demonstrating that the inert ingredients also are in acute oral toxicity Category III see Confidential Appendix). The EPA Peroxy Compounds RED (dated 12/1993), lists both acute oral toxicity and acute dermal toxicity in Toxicity Category III for Hydrogen Peroxide; and lists acute oral toxicity in Toxicity Category III and acute dermal toxicity in Toxicity Category II for Peroxyacetic Acid. The reviewer also notes that dermal irritation was placed in Toxicity Category I (Corrosive) for both Hydrogen peroxide and Peroxyacetic Acid. All subsequent documents for products containing these two active ingredients, cite the EPA Peroxy Compounds RED (dated 12/1993) in lieu of acute toxicity studies. In addition, the applicant cited acute oral toxicity for each individual substance contained in the formulated product, Jet-Ag, but did not submit any data for the formulated product (see ECETOC, 2001; and Table 1 in the Confidential Appendix).

## CONCLUSIONS

The request to change the precautionary statement on the product label for Jet-Ag (EPA Reg. No. 81803-6) from "*May be fatal if swallowed*" to "*Harmful if swallowed*" is acceptable, and agrees with the Toxicity Category III classification for both Hydrogen Peroxide and Peroxyacetic Acid as specified in the Peroxy Compound RED of 1993. Due to the Toxicity Category I (Corrosive) classification for dermal irritation, the precautionary statement "*Causes skin burns...*" must remain on the Jet-Ag product label. Due to the corrosive effect upon the skin, it is unlikely that the active ingredients would be appreciably absorbed through the skin. Therefore, the request to change the existing precautionary statement "*May be harmful if absorbed through skin....*" May be removed. Although the information cited by the applicant for each ingredient in the formulation indicated that each ingredient could be classified individually in Toxicity Category III for acute oral toxicity, it cannot be assumed that the formulated product containing a mixture of these ingredients would not have unknown additive and/or synergistic effects that would result in lower Toxicity Categories for acute dermal toxicity and dermal irritation.

Alpha Methyl Mannoside

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cc: R. S. Jones, M. Rexrode, A. Horansky, BPPD Science Review File, IHAD/ARS

R. S. Jones, FT, PY-S: 06/12/17

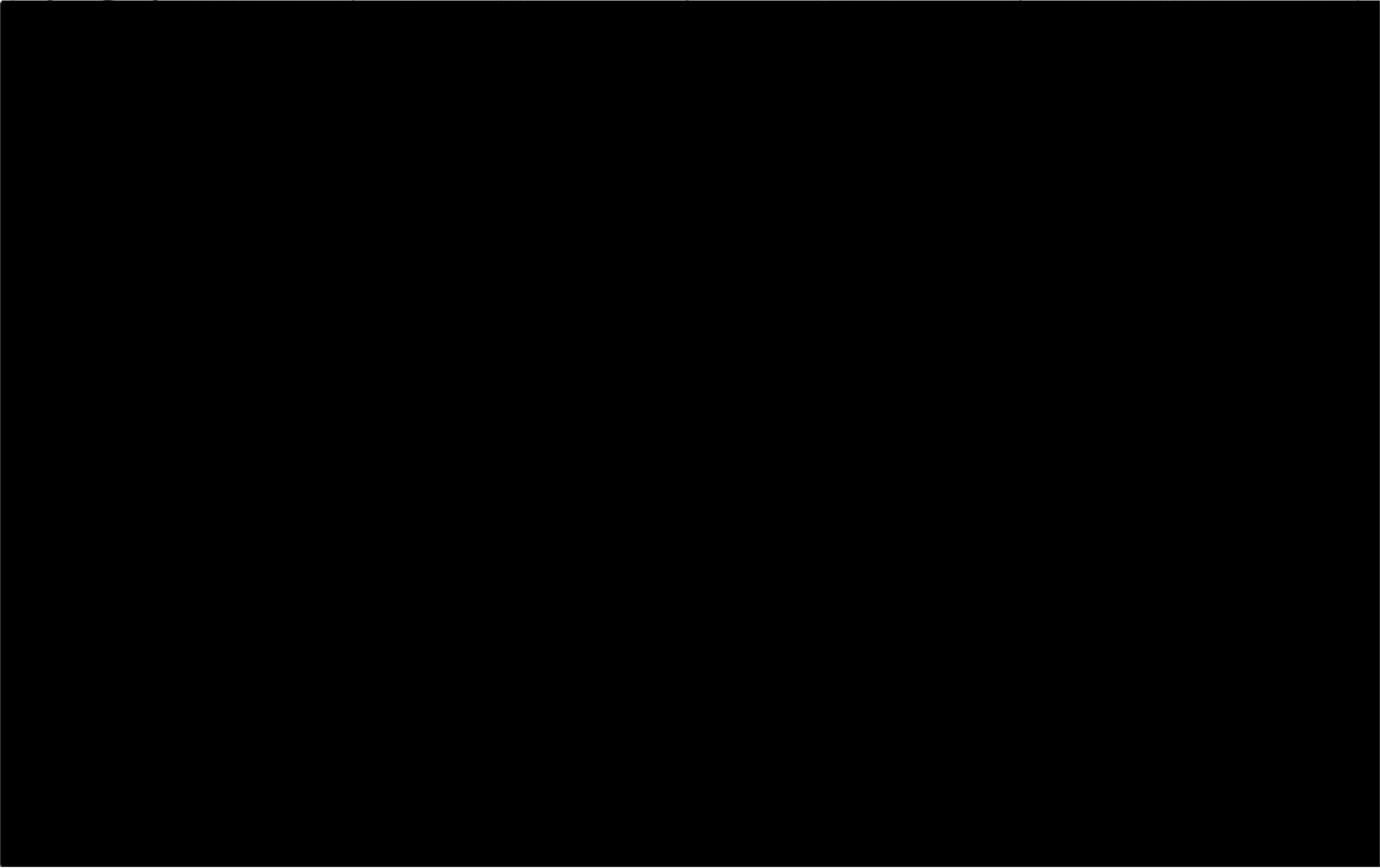
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## CONFIDENTIAL APPENDIX

Information cited by applicant

Table 1. Acute Oral Toxicity of Jet-Ag			
Compound	Wt. % in formulation	Purpose in formulation	Oral LD <sub>50</sub> (mg/kg bw)
Peroxyacetic acid (PAA)	4.9	Active	1540
Hydrogen peroxide	26.5	Active	2000



\*Inert ingredient information may be entitled to confidential treatment\*